UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,091	03/26/2004	Todd K. Whitehurst	AB-276U	8209

7590 09/01/2005

Advanced Bionics Corporation
12740 San Fernando Rd.
Sylmar, CA 91342

EXAMINER	
ROSENZWEIG, JASON	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,091	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Jason E. Rosenzweig	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08022004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11,12,13,14,15,19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zabara (US 4702254).

3. Regarding claim 11, Zabara discloses: A method of treating a patient with a movement disorder, comprising: providing at least one system control unit that generates stimulating pulses in accordance with prescribed parameters, which stimulating pulses are infusion pulses (see abstract); providing at least one catheter connected to the at least one system control unit (Fig 3, Element 56), which catheter includes at least one discharge portion; implanting the at least one catheter discharge portion adjacent to at least one vagus nerve to be stimulated (Fig. 3, Element 24 or 22); implanting the at least one system control unit at a location remote from the at least one tissue to be stimulated (Fig 4 and 5); tunneling the catheter subcutaneously to the system control unit location (See abstract); and delivering via the infusion pulses at least one drug to the at least one vagus nerve (See Abstract), thereby affecting a movement disorder in order to at least in part alleviate the movement disorder of the

patient being treated. Based upon the definition given by Applicant for stimulation pulses (Pg. 8, Paragraph 41 of application) it is assumed that stimulation pulses may include the use of electrical stimulation or drug infusion.

4. Regarding claim 12, Zabara discloses: The method of claim 11 wherein the system control unit is further connected to at least one electrode (Fig 3, Element 48 and 50), and wherein the stimulus further comprises electrical stimulation delivered via the at least one electrode (Fig. 3, Element 22 and 24).

5. Regarding claim 13, Zabara discloses: The method of claim 12 wherein the electrical stimulation is delivered at a frequency less than about 100 Hz (Pg. 5, Paragraph starting at Ln. 11). 30-300 cycles per second is the same as a frequency of 30-300hz, which can include frequencies less than about 100 Hz.

6. Regarding claim 14, Zabara discloses: The method of claim 11 wherein the stimulation increases activity of the at least one vagus nerve (Reads on claim 12).

7. Regarding claim 15, Zabara discloses: The method of claim 14 wherein the stimulation is drug stimulation provided by at least a neural depolarizing agent. A neural depolarizing agent could include the use of applying a voltage across a sodium ion or calcium ion channel and altering the voltage potential across a cell membrane. As per the applicants description of a stimulation pulse drug therapy could include the use of solely electrical therapy (Pg. 8, Paragraph 41 of application).

8. Regarding claim 19, Zabara discloses: The method of claim 11 further comprising sensing at least one condition and using the at least one sensed condition to automatically determine the stimulus to apply (Pg. 6, Line 39).

9. Regarding claim 20, Zabara discloses: The method of claim 19 wherein the at least one sensed condition is electrical activity of a neural population (Pg. 3, Ln. 3).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1,2,3,4,5,7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rice (US 6227203) in view of Loeb (US 6051017).

13. Regarding claim 1, Rice discloses: A method of treating a patient with a movement disorder (Claim 1), comprising: providing at least one stimulator for controlling delivery of at least one stimulus via at least one infusion outlet (Fig 3), wherein the at least one stimulus comprises stimulation via at least one drug delivered through the at least one outlet (Fig 3); implanting the at least one stimulator entirely or substantially in the carotid sheath; and, using the stimulator, applying the at least one

stimulus to at least one vagus nerve in order to at least in part alleviate the movement disorder of the patient being treated (Claim 15). Applicant disclosed a device with the above characteristics, additionally comprised of a leadless stimulator to aid in miniaturization; Rice does not disclose the use of a leadless stimulator. Loeb discloses a fully implantable miniature stimulator (Fig 4 and 6), which is leadless. It is noted that in order to stimulate the vagus nerve one would have to penetrate or implant a device under the carotid sheath. It would be obvious to one of ordinary skill in the art to modify Rise's disclosure in view of Loeb in order to miniaturize a Neurostimulation device to reduce the amount of surgery required to implant the device.

14. Regarding claim 2, In reference to Rice in view of Loeb in Claim 1, Rice discloses: The method of claim 1 wherein the stimulator further includes at least two electrodes (Fig 3, Element 38 and 40), and wherein the stimulus further comprises electrical stimulation delivered via the at least two electrodes (Pg. 5, Ln. 20). As both the Rice disclosure and the Loeb disclosure contain at least two electrodes it would be obvious to one of ordinary skill in the art to miniaturize Rice's device by implementing leadless stimulators as discussed by Loeb inorder to have a smaller implantable device.

15. Regarding claim 3, In reference to Rice in view of Loeb in Claim 1, Rice substantially discloses: The method of claim 2 wherein the electrical stimulation is delivered at a frequency less than about 100 Hz (Pg. 9, Ln. 36). A range of 2-100/hz encompasses a frequency less than about 100 Hz. It would have been obvious to one of ordinary skill in the art to modify Rice's disclosure in view of Loeb as discussed in claim 1 and further including the use of electrical stimulation at a frequency less than

about 100 Hż as discussed by rice in order to stimulate the vagus nerve to treat motor dysfunctions.

16. Regarding claim 4, In reference to Rice in view of Loeb in Claim 1, Rice substantially discloses: The method of claim 1 wherein the stimulation increases activity of the at least one vagus nerve (Fig. 13, Element 400). It would have been obvious to one of ordinary skill in the art to modify Rice's disclosure in view of Loeb as discussed in claim 1 and further including the use of electrical stimulation on the vagus nerve as discussed by rice in order to stimulate the vagus nerve to treat motor dysfunctions with a smaller leadless stimulator.

17. Regarding claim 5, In reference to Rice in view of Loeb in Claim 1, Rice substantially discloses: The method of claim 4 wherein the stimulation is drug stimulation provided by at least a neural depolarizing agent (Pg. 8, Table 3). It would have been obvious to one of ordinary skill in the art to modify Rice's disclosure in view of Loeb as discussed in claim 1, further including the use smaller leadless stimulator which includes the use of drug delivery as a stimulation method on the vagus nerve as discussed by rice in order to stimulate the vagus nerve to treat motor dysfunctions.

18. Regarding claim 7, In reference to Rice in view of Loeb in Claim 1, Rice discloses: The method of claim 4 wherein the stimulation is drug stimulation provided by at least one of an excitatory neurotransmitter, an excitatory neurotransmitter agonist, an inhibitory neurotransmitter antagonist, an agent that increases the level of an excitatory neurotransmitter, and an agent that decreases the level of an inhibitory neurotransmitter (Table 1 and 3). It would have been obvious to one of ordinary skill in

the art to use these drugs in a miniaturized version of Rice's device in view of Loeb leadless stimulator.

19. Regarding claim 9, In reference to Rice in view of Loeb in Claim 1, Rice discloses: The method of claim 1 further comprising sensing at least one condition and using the at least one sensed condition to automatically determine the stimulus to apply (Fig. 13, 14, 15, and 16). It would be obvious to implement a closed loop feedback system into a miniaturized stimulator as discussed by Rice in view of Loeb.

20. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rice in view of Loeb as applied to claims 1,2,3, and 9 above, and further in view of Ishukawa (US 6464687).

21. Regarding claim 10, In reference to Rice in view of Loeb, Ishukawa discloses: The method of claim 9 wherein the at least one sensed condition is acceleration (Pg. 4, Ln. 64). Applicant specifically stated the use of acceleration as at least one of the sensed conditions, it would be obvious to one of ordinary skill in the art to modify Rice's device as per claim 1 to include a miniaturized leadless stimulator and in further view of Ishukawa to implement a accelerometer in order to have the capability to sense a particular physical signal, such as acceleration in order to detect a level of motor function or dysfunction.

22. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara in view of Rice.

23. Regarding claim 17, Zabara discloses a stimulation device as described in claim 1 above however does not disclose a method for drug delivery. In view of the teachings of Rice in his disclosure of a stimulation and drug infusion device, it would be obvious to one of ordinary skill in the art to implement a drug delivery system within an electrical neurostimulation device. Rice discloses: The method of claim 14 wherein the stimulation is drug stimulation provided by at least one of an excitatory neurotransmitter (Table 3), an excitatory neurotransmitter agonist (Table 3), an inhibitory neurotransmitter antagonist (Table 3), an agent that increases the level of an excitatory neurotransmitter (Table 3), and an agent that decreases the level of an inhibitory neurotransmitter (Table 3).

24. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rice in view of Loeb as applied to claims 1,2,3,4, and 5 above, and further in view of Aebischer (US 6179826) et al.

25. Regarding claims 6 and 8, Aebischer discloses: The method of claim 5 wherein the neural depolarizing agent is succinylcholine, which is an acetylcholine Agonist (Pg. 6, Paragraph Starting on Ln. 4). Bethanechol is a stimulator, which is considered a biological factor as described in the reference paragraph above. It would be obvious to one of ordinary skill in the art to further modify Rice's device as discusses above including the use of a leadless stimulator and further specifically utilizing Succinylcholine since this is simply a acetylcholine agonist which is already implemented in Aebisher's device. Also Bethanechol is a stimulator, which could be

considered a biological factor, which is released through the delivery system discussed by Aebischer.

26. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara in view of Aebischer.

27. Regarding claims 16 and 18, Zabara discloses an electrical neurostimulation device but does not disclose a drug delivery system. Aebischer discloses implantable therapy system and method for controlled local delivery of a biologically active factor. The examiner takes official notice that other devices such as the one disclosed of by Rice discloses a device that performs both electrical stimulation and drug delivery however the use of Acetylcholine or it's agonist is not mentioned in Rice's device. In view of Aebischer it would be obvious to one of ordinary skill in the art to combine an electrical stimulation device with a drug delivery system, which could locally deliver active biological factors such as Acetylcholine, and it's agonists. (Pg. 6, Ln. 4). It should be noted that active biological factors could include the use of acetylcholine and/or bethanechol.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Rosenzweig
Patent Examiner
Art Unit 3762

Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3762

***